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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,830	08/26/2002	Crisanto Gutierrez-Armenta	BTG0004-100	2262

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,830	GUTIERREZ-ARMENTA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,12-19,21-24 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,12-19,21-24 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22707*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on January 18, 2007 has been entered.

Claims 4, 7-11, 20 and 25-46 are cancelled.

Claims 1, 5-6, 12, 15, 22 and 47 are currently amended.

Claims 1-3, 5-6, 12-19, 21-24 and 47 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-6, 12-13, 15, 22-24 and 47 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

Applicant's arguments filed January 18, 2007 have been fully considered but they are not persuasive.

Applicant maintains that the recitation that the plant cell of claim 1 is transformed with a nucleic acid comprising a sequence encoding SEQ ID NO:2, or a functional part thereof, or a sequence having at least 70% homology is sufficient to establish that Applicants were in possession of the claimed invention. Applicant also maintains that the recitation of features common to DP proteins, such as dimerization with a plant E2F

protein or peptide to increase E2F activity in the plant cell and structural features such as the DNA binding domain, the heterodimerization domain, and the nuclear localization are a recitation of features common to members of the genus, which features constitute a substantial portion of the genus. Applicant additionally maintains that possession of the claimed invention has been demonstrated by recitation of a sequence (SEQ ID NO:2) in combination with functional activity. Applicants also points out that a single disclosed specie may adequately support the description of a genus, and Applicant maintains that the disclosure of additional species is not warranted here because the claims recite common attributes and features of the elements possessed by the members in view of the specie disclosed. Applicant further points out that the written description requirement is met so long as the invention is described in the specification as broadly as it is claimed. (reply pages 12-13)

Applicant's arguments are unconvincing. The invention is not described in the specification as broadly as it is claimed. The recitation of structure and function in the claims does not describe the claimed invention because the recited genus has not been described. Recitation of features common to DP proteins of the prior art, such as dimerization with a plant E2F protein or peptide to increase E2F activity in the plant cell and structural features such as the DNA binding domain, the heterodimerization domain, and the nuclear localization, are not a recitation of features common to members of the genus here which features constitute a substantial portion of the genus, as the sequences encoding these proteins are not members of the genus, i.e. they do not encode proteins having at least 70% homology to SEQ ID NO:2. Further, it has not been established that SEQ ID NO:2 has all the of the features common to DP proteins of the prior art.

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus, as Applicant has described only a single specie. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). Unpredictability in the results obtained from species other than those specifically enumerated (SEQ ID NO:2) was evidenced by Hiebert S. W. et al., Magyar Z. et al., Dynlacht B.D. et al., Sawado T et al., Wu CL et al. and Mariconti L. et al. as set forth at pages 10-12 of the office action mailed March 15, 2005.

With respect to Applicant's assertion that possession may be demonstrated by the mere recitation of a sequence in combination with functional activity, See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617:

Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to

antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

Claims 1-3, 5-6, 12-13, 15-19, 21-24 and 47 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record.

Applicant's arguments filed January 18, 2007 have been fully considered but they are not persuasive.

Applicant maintains that one skilled in the art would, based on Applicants' specification, be able to make any of the nucleic acids required by the rejected claims without undue experimentation, as the specification teaches the function of these domains, and they are demonstrated to be present in other DP proteins. Applicant also points out that the specification teaches ample methods of verifying the activity of the proteins. (reply pages 14-15).

Applicant's arguments are unconvincing. The outstanding rejection was not predicated on a failure to provide guidance with respect to the general practice of techniques for verifying DP protein activity that are known to and/or within the abilities of those skilled in the art. The outstanding rejection was predicated in part on a failure to provide guidance with respect to the specific practice of such techniques, i.e. with respect to which sequences to make and test, and with respect to which functional assays to apply to which sequences, in order to discriminate between those sequences that function as

desired and those that do not. Absent such guidance, one skilled in the art would have to isolate from undisclosed sources and/or synthesize each of the myriad sequences encompassed by the claims and then determine the specific function of each in order to discriminate between those sequences that function as desired and those that do not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. Further, reciting that the proteins or peptides encoded by the nucleic acid comprise at least one structural domain of known function that has been demonstrated as being present in other DP proteins does not provide the required guidance, as the functional contribution of a domain to the protein that comprises it is context dependent.

Applicant also maintains that the Office Action does not specifically point out which particular aspect requires undue experimentation. Applicant points to the Office Action dated March 15, 2005, which asserts that the invention is not enabled because "the effect of expressing in a cell a DP protein, alone or in combination with an E2F protein, is unpredictable, since different members of both the DP protein family and the E2F protein family vary with respect to their specific functions, and with respect to how they function when expressed independently and when coexpressed." Applicant points out that the Office Action cites six references which purportedly supports the Examiner' s position, only two of which relate to plant DP proteins, and maintains that the fact that DP proteins may have many different functions, particularly in non-plant cells, is wholly irrelevant in determining whether one skilled in the art can practice the claimed invention in plant cells without being required to perform undue experimentation. (reply page 15)

Applicant's arguments are unconvincing. The variability of function observed for different types of nonplant DP proteins in nonplant cells is relevant to determining whether undue experimentation is required to carry out the claimed method in plant cells, because both the cell cycle and the proteins whose activity is required for its progression are conserved across the eukaryotic kingdoms, and because variability of structure and function have also been observed for different types of plant DP proteins. The cited references need not teach or suggest that observations pertaining to animal DP proteins are what would also be expected of plant DP proteins, as the conservation of both the cell cycle and the proteins whose activity is required for its progression is well established in the prior art.

Applicant additionally argues that Magyar Z. et al. and Mariconti L. et al. do not teach or suggest that Applicant's claimed invention does not work or would require undue experimentation, as Magyar Z. et al. and Mariconti L. et al. are directed to sequences encoding DP proteins obtained from *Arabidopsis thaliana*, and are silent with respect to Applicant's claimed invention which makes use of sequences encoding DP proteins obtained from wheat (reply page 15).

Applicant's arguments are unconvincing. Neither Magyar Z. et al. nor Mariconti L. et al. were cited for any specific teachings with respect to the functionality of or use of wheat DP proteins. Both Magyar Z. et al. and Mariconti L. et al. were cited to support the general assertion that the effect of expressing in a cell a DP protein, alone or in combination with an E2F protein, is unpredictable, since different members of both the DP protein family and the E2F protein family vary with respect to their specific

functions, and with respect to how they function when expressed independently and when coexpressed. Given that the effect of expressing in a cell a DP protein, alone or in combination with an E2F protein, is unpredictable, and given that the genus of sequences recited in the claims appear to encode polypeptides that belong to the DP family of proteins, the effect of expressing in a cell any member of the genus of sequences recited in the claims is also unpredictable. Furthermore, the rejected claims are not limited to the use of sequences encoding DP proteins obtained from wheat.

Applicant also argues that Sandler S.J. et al., van der Krol A.R. et al. and Waterhouse et al. do not teach or suggest that Applicant's claimed invention does not work or would require undue experimentation, as the principals set forth in Sandler S.J. et al., van der Krol A.R. et al. and Waterhouse et al. were well known to those of skill in the art prior to Applicant's filing date, and the general principals of antisense sequence construction and use in plants is broadly appreciated in the art. Applicant also points to Shewmaker C.K. et al. (US Patent No. 5,107,065, issued April 21, 1992) cited in the specification which teaches the general principals of the construction of antisense compounds (reply pages 16-17).

Applicant's arguments are unconvincing. The outstanding rejection was not predicated on a failure to provide guidance with respect to the general practice of techniques that are known to and/or within the abilities of those skilled in the art. The outstanding rejection was predicated in part on a failure to provide guidance with respect to the specific practice of such techniques, i.e. with respect to which nucleotide sequences to express in a plant as antisense transcripts, or how to express them such that plant

growth, gene expression, DNA replication, cell cycle progression, differentiation and development could be controlled in a particular manner. Such guidance is necessary because methods for inhibiting the expression of endogenous genes using antisense technology are unpredictable as set forth in Sandler S.J. et al., van der Krol A.R. et al. and Waterhouse et al. Absent such guidance one skilled in the art would have to test each of the myriad sequences encompassed by the claims for its specific effect on plant growth, gene expression, DNA replication, cell cycle progression, differentiation and development in order to discriminate between those sequences that function as desired and those that do not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. Furthermore, the disclosure of the general principals of the construction of antisense compounds by Shewmaker C.K. et al. does not provide guidance with respect to the specific practice of such techniques using the nucleotide sequences encompassed by the claims.

Applicant points out that claims 12, 13, 15-24 and 47 are directed to compounds and not methods, and that undue experimentation is not required to make the claimed compounds, as nucleic acids are routinely made by those skilled in the art (reply page 17).

The Examiner maintains that Applicant's comments are inapposite to the outstanding rejection, which is not predicated on the ability of those skilled in the art to make nucleic acid compounds.

Applicant also maintains that any use of the compounds is sufficient for the purpose of their enablement, that the claimed compounds can be used to express a

protein, to detect nucleic acid sequences, or as primers for DNA amplification, and that undue experimentation is not required for any of these uses (reply pages 17-18).

The Examiner maintains that the asserted uses are not enabled, as the specification does not provide sufficient guidance with respect to how to use any particular protein expressed from any of the claimed sequences, or with respect to how to use any of the claimed sequences to detect any particular nucleic acid sequences, or with respect to how to use any of the claimed sequences to amplify any particular DNA fragment.

Applicant further argues that argues that Gillespie D. does not teach or suggest that Applicant's claimed invention does not work or would require undue experimentation, as the principals set forth in Gillespie D. were well known to those of skill in the art prior to Applicant's filing date, and the optimization of hybridization conditions was routinely practiced. Applicant also maintains that the selection of probes does not involve the examination of a myriad of possibilities as it is limited by the sequence from which the probe is derived (SEQ ID NO:1) (reply pages 18-19)

Applicant's arguments are unconvincing. The outstanding rejection was not predicated on a failure to provide guidance with respect to the general practice of techniques that are known to and/or within the abilities of those skilled in the art. The outstanding rejection was predicated in part on a failure to provide guidance with respect to the specific practice of such techniques, i.e. with respect to which specific nucleotide sequences to use as DNA probes, the conditions for their use, and the specific targets that can be detected using these probes. Such guidance is necessary because the conditions for

using a sequence as a probe are unpredictable as set forth in Gillespie D. Absent such guidance one skilled in the art would have to test each of the myriad sequences encompassed by the claims under a variety of different conditions in order to determine which probe sequences are useful for the detection of particular target sequences and which are not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. Further, the selection of probes does involve the examination of a myriad of possibilities, because the claims encompass multiple nucleotide sequences that differ in both primary sequence and length (10 or more contiguous nucleotides or at least 18 contiguous nucleotides of SEQ ID NO:1, which consists of 1089 contiguous nucleotides), and because the selection of a probe or primer also requires the selection of target sequences.

Claim Rejections - 35 USC § 102

Claims 17, 18 and 19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Gillaspy G.E et al., GenEmbl Accession No. U39059, 18 November 1996, for the reasons of record.

Applicant's arguments filed January 18, 2007 have been fully considered but they are not persuasive.

Applicant maintains that Gillaspy G.E et al. do not anticipate the rejected claims because they do not teach every feature recited in the claims.

Applicant points out that a sequence alignment of the Gillaspy sequence and SEQ ID NO:1 shows only that the two sequences possess 52 contiguous adenosines in common in the poly A tail and 8 other bases in common. Applicant maintains that the

Gillaspy sequence does not represent a nucleic acid probe because it has only limited GC content and does not appear likely to act as a probe at a reasonable stringency. Applicant also maintains that one skilled in the art would be very unlikely to select a probe that contains a sequence that is quite clearly not in any way specific to a particular sequence. Applicant additionally points out that "a nucleic acid molecule" is not recited in the claim; rather, "probe" is recited in the claim. Applicant maintains that the term "probe" actually means something to one skilled in the art and is distinguishable as a subtype of a nucleic acid molecule. Applicant points out that have inherent features such as those discussed above which render them useful as probes, and maintains that one skilled in the art would be very unlikely to select a probe that contains a 52-base polyA sequence that would quite clearly not be specific to a plant DP sequence, let alone any other sequence. (reply pages 6-7)

Applicant's arguments are unpersuasive. In response to applicant's argument that the reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., ability to hybridize to a specific target sequence under conditions of specified stringency and specificity for a plant DP sequence) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, a nucleic acid molecule is recited in the rejected claims, as the nucleic acid probe of claim 17 comprises " a double or single stranded DNA molecule comprising 10 or more contiguous nucleotides", and the probes of claims 18 to 19 comprise nucleotide bases.

Gillaspy G.E et al. anticipate the claimed invention because Gillaspy G.E et al. teach a DNA sequence consisting of 60 contiguous nucleotides of SEQ ID NO:1 that are not selected from nucleotides encoding amino acids 70 to 136. Accordingly the DNA sequence taught by Gillaspy G.E et al. comprises 10 or more contiguous nucleotides of SEQ ID NO:1 that are not selected from nucleotides encoding amino acids 70 to 136, at least 18 contiguous bases of SEQ ID NO:1, 30 to 100 contiguous bases of SEQ ID NO:1, and 10 to 20 contiguous bases of SEQ ID NO:1.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

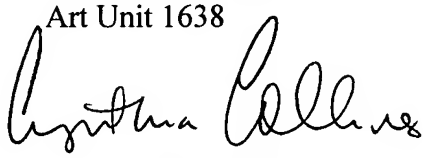
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638



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